

# PATENT COOPERATION TREATY

Alston & Bird

AUG 23 2006

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

Received By

To:

ALSTON & BIRD LLP  
Attn: Kirk, Trent A.  
Bank of America Plaza  
101 South Tryon Street, Suite 4000  
Charlotte, NC 28280-4000  
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT AND  
THE WRITTEN OPINION OF THE INTERNATIONAL  
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

22/08/2006

Applicant's or agent's file reference

47956/310088

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2006/013129

International filing date  
(day/month/year)

06/04/2006

Applicant

ALVEOLUS, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

## Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

**Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

## 4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

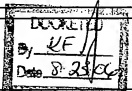
See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Elisabeth Vonk



## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 47956/310088	<b>FOR FURTHER ACTION</b> see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2006/013129	International filing date (day/month/year) 06/04/2006	(Earliest) Priority Date (day/month/year) 08/04/2005

Applicant

ALVEOLUS, INC.

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (see Box No. III)

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant  
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant  
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1  
☒ as suggested by the applicant  
☐ as selected by this Authority, because the applicant failed to suggest a figure  
☐ as selected by this Authority, because this figure better characterizes the invention  
b. ☐ none of the figures is to be published with the abstract

## INTERNATIONAL SEARCH REPORT

 International application No  
 PCT/US2006/013129

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. A61F2/06 A61F2/04 A61F5/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/72239 A (NEOVASC, INC.; SHALEV, ILAN; TSEHORI, JONATHAN; DARVISH, NISSIM) 4 October 2001 (2001-10-04)  page 21, line 23 - line 29; figures 2, 3A-D, 8	1, 2, 4-9, 12, 13, 15, 16, 26, 27, 30-32
A	----- WO 2005/011527 A (JOTEC GMBH; KAUFMANN, RALF; BOGENSCHUETZ, THOMAS) 10 February 2005 (2005-02-10) page 18, paragraph 3 - page 19, paragraph 2; figure 2  ----- -/--	17, 18, 20, 22
X	WO 2005/011527 A (JOTEC GMBH; KAUFMANN, RALF; BOGENSCHUETZ, THOMAS) 10 February 2005 (2005-02-10) page 18, paragraph 3 - page 19, paragraph 2; figure 2	1, 2
A	----- -/--	4, 7, 26
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.		
<input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "Z" document member of the same patent family		
Date of the actual completion of the international search  14 August 2006		Date of mailing of the international search report  22/08/2006
Name and mailing address of the ISA/ European Patent Office, P.B. 5618 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016		Authorized officer  Neumann, E

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/013129

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 197 54 747 A1 (IMPAG GMBH MEDIZINTECHNIK, 74424 BUEHLERTANN, DE) 17 June 1999 (1999-06-17) column 3, line 39 - line 60; figures	1,2,5
A		6-9, 26-28,32
X	US 2003/040803 A1 (RIOUX ROBERT F ET AL) 27 February 2003 (2003-02-27)	7-9, 11-13, 15,16, 26,27, 30-32
A	paragraphs [0034], [0036]; figures	1,2,4,5, 19
X	US 2003/212450 A1 (SCHLICK TILMAN) 13 November 2003 (2003-11-13)	7-9,12, 13,16, 25-27, 30-32
A	paragraph [0030] - paragraph [0032]; figures 2-4	1-5
X	US 2003/130611 A1 (MARTIN ERIC C) 10 July 2003 (2003-07-10) paragraphs [0025], [0030]; figure 3	7-9,16, 25-27,32
A		1,2,4

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2006/013129

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 33-36  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/013129

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0172239 A	04-10-2001	AU 4678101 A	08-10-2001
		AU 2006202444 A1	29-06-2006
		BR 0109681 A	22-06-2004
		CA 2404330 A1	04-10-2001
		CN 1430490 A	16-07-2003
		EP 1276437 A2	22-01-2003
		JP 2003527924 T	24-09-2003
		MX PA02009515 A	14-05-2004
		US 2005267567 A1	01-12-2005
		US 6953476 B1	11-10-2005
WO 2005011527 A	10-02-2005	DE 10335649 A1	24-02-2005
		EP 1648342 A1	26-04-2006
DE 19754747 A1	17-06-1999	NONE	
US 2003040803 A1	27-02-2003	CA 2458117 A1	06-03-2003
		EP 1420720 A2	26-05-2004
		WO 03017871 A2	06-03-2003
US 2003212450 A1	13-11-2003	AT 312572 T	15-12-2005
		DE 10221076 A1	27-11-2003
		EP 1360942 A1	12-11-2003
		JP 2003325674 A	18-11-2003
		US 2005182481 A1	18-08-2005
US 2003130611 A1	10-07-2003	NONE	

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

#### FOR FURTHER ACTION

See paragraph 2 below

International application No.  
PCT/US2006/013129

International filing date (day/month/year)  
06.04.2006

Priority date (day/month/year)  
08.04.2005

International Patent Classification (IPC) or both national classification and IPC  
INV. A61F2/06 A61F2/04 A61F5/00

Applicant  
ALVEOLUS, INC.

#### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and Industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

#### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaage  
NL-2280 HV Rijswijk - Pays Bas  
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl  
Fax: +31 70 340 - 3016

Date of completion of  
this opinion

see form  
PCT/ISA/210

Authorized Officer

Neumann, E

Telephone No. +31 70 340-3028





**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2006/013129

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 33-36

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- ☒ no international search report has been established for the whole application or for said claims Nos. 33-36
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13<sup>ter</sup>.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2006/013129

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**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	3,10,14,17-24,28,29
	No: Claims	1,2,4-9.11-13,15,16,25-27,30-32
Inventive step (IS)	Yes: Claims	
	No: Claims	1-32
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item V.**

1 Reference is made to the following documents:

- D1: WO 01/72239 A (NEOVASC, INC; SHALEV, ILAN; TSEHORI, JONATHAN; DARVISH, NISSIM) 4 October 2001 (2001-10-04)
- D2: WO 2005/011527 A (JOTEC GMBH; KAUFMANN, RALF; BOGENSCHUETZ, THOMAS) 10 February 2005 (2005-02-10)
- D3: DE 197 54 747 A1 (IMPAG GMBH MEDIZINTECHNIK, 74424 BUEHLERTANN, DE) 17 June 1999 (1999-06-17)
- D4: US 2003/040803 A1 (RIOUX ROBERT F ET AL) 27 February 2003 (2003-02-27)
- D5: US 2003/212450 A1 (SCHLICK TILMAN) 13 November 2003 (2003-11-13)
- D6: US 2003/130611 A1 (MARTIN ERIC C) 10 July 2003 (2003-07-10)

**2 INDEPENDENT CLAIM 1**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (the references in parentheses applying to this document; see page 21, lines 23 - 29 and figures 2, 3D, 8):

A flexible stent (100,320,800) *suitable* for implanting in the soft duodenum of a patient and maintaining the patency of a stricture in a wall of the duodenum, the stent (100,320,800) comprising:

a stent region (figures 2, 3D and 804) having a stiffness configured to hold the stricture open after implantation;

a first transition region (200, figures 3D, 8) extending radially outwardly and axially away from an end of the stent region and defining a first open end, the first transition region having a stiffness less than the stiffness of the stent region (see page 21, lines 23 - 29); and

a second transition region (202, figures 3D, 8) extending radially outwardly and axially away from an opposite end of the stent region and defining a second open end opposite the first open end, the second transition region having a stiffness less than the stiffness of

the stent region (see page 21, lines 23 - 29); wherein the stent region defines in cross-section at least one concave portion (see figures 2, 9D-F), the concave portion being adapted to receive the stricture when the stent is properly positioned in the duodenum and to maintain the stent in position after implantation so as to prevent migration of the stent along the duodenum.

Although the stent is not explicitly described to be placed in the duodenum it comprises all the technical features of claim 1 and is suitable to be placed in the duodenum of a patient.

2.2 The attention of the applicant is drawn to the fact that each of the documents D2 and D3 (see the relevant passages in the search report) discloses all the technical features of claim 1, and are prejudicial for its novelty as well.

### **3 INDEPENDENT CLAIM 7**

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 7 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (the references in parentheses applying to this document; see figure 3D):

A flexible stent (320) for positioning within a body lumen comprising:  
a stent region having proximal and distal ends and an aperture defined therethrough;  
a first transition region extending outwardly from an end of the stent region and at least a portion of the first transition region configured in a helix comprising a plurality of turns, the first transition region having a larger diameter than at least a portion of the stent region and having an aperture defined therethrough; and  
a second transition region extending outwardly from an opposite end of the stent region, the second transition region having a larger diameter than at least a portion of the stent region and having an aperture defined therethrough,  
wherein each of the apertures of the first and second transition regions and stent region are substantially collinear, and wherein each of the first and second transition regions are capable of expanding from a first diameter prior to being deployed into the lumen to a larger second diameter after being deployed into the

lumen.

#### **4 INDEPENDENT CLAIM 26**

- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 26 is not new in the sense of Article 33(2) PCT.  
Document D1 discloses (the references in parentheses applying to this document; see figure 3D):

A flexible stent (320) for positioning within a body lumen comprising:  
a stent region and a pair of transition regions extending from respective ends of the stent region, each of the transition and stent regions defining an aperture therethrough, wherein both of the transition regions is configured in a helix comprising a plurality of turns, and wherein the stent region is capable of expanding to conform to a stricture and each of the transition regions is capable of expanding to conform to the lumen proximally and distally of the stricture.

- 5 The attention of the applicant is drawn to the fact that each of the documents D4, D5 and D6 (see the relevant passages in the search report) discloses all the technical features of claims 7 and 26, and are prejudicial for their novelty as well.

#### **6 DEPENDENT CLAIMS 2 - 6, 8 - 25 and 27 - 32**

6.1 Dependent claims 2 - 6, 8, 9, 11 - 13, 15 - 20, 22, 24, 25, 27, 28 and 30 - 32 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see for example documents D1 , D3, D4 and D5 and the corresponding passages cited in the search report.

6.2 The additional features of claims 10, 14, 21, 23 and 29 relate to design alternatives which are well-known to the skilled practitioner who would readily employ them in order to

solve the respective technical problems posed. Therefore, these claims do not meet the criteria of Article 33(1) PCT.

**Re Item VII.**

1. Independent claims 1, 7 and 26 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(II) PCT).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

**Re Item VIII.**

1. Although claims 1, 7 and 26 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
2. Independent claim 1 is not clear, contrary to Article 6 PCT. In claim 1, the stent region should define in cross-section at least one concave portion. However, according to the description and the accompanying drawings it is clear that the stent region as such is concave between the transition portions (see page 7, lines 1 - 5) and not its cross-section.